K081998

JUL - 9 2009

510(k) Summary

Electronic Waveform Lab Inc.'s H-Wave® Sport

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Electronic Waveform Lab, Inc.
16168 Beach Boulevard
Suite 232
Huntington Beach, CA 92647

Phone: (800) 874-9283
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Contact Person: Ryan P. Heaney, President

Date Prepared: February 3, 2009

Name of Device

H-Wave® Sport

Common or Usual Name/Classification Name

Powered muscle stimulator

Predicate Devices

H-Wave®, Electronic Waveform Lab, Inc. (K915230)
Compex® Sport, Compex S.A. (K011880)

Intended Use / Indications for Use

The H-Wave Sport is intended for muscle conditioning by stimulating muscle in order to improve or facilitate muscle performance. The H-Wave Sport is not intended to be used for therapy or treatment of medical diseases or medical conditions..

Technological Characteristics

The H-Wave® Sport consists of: a portable, battery operated neuromuscular stimulator with two channels, two sets of lead wires, two packages of self-adhesive electrodes and a battery charger. The H-Wave® Sport stimulator is equipped with two simple dials that increase the intensity for each channel, output jacks for each channel, and a battery level indicator.

Performance Data

The company performed laboratory bench testing to evaluate the H-Wave Sport device. In all instances, the H-Wave® Sport functioned as intended and the results observed were as expected. Performance data supports the use of low-frequency stimulation for endurance and active recovery.

Substantial Equivalence

The H-Wave® Sport is as safe and effective as the cleared H-Wave® and the cleared Compex® Sport. The H-Wave® Sport has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the H-Wave® Sport and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the H-Wave® Sport is as safe and effective as the predicate devices. Thus, the H-Wave® Sport is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Electronic Waveform Lab, Inc.
% Mr. Ryan P. Heaney, President
16168 Beach Boulevard
Suite 232
Huntington Beach, California 92647

JUL - 9 2009

Re: K081998
Trade/Device Name: H-Wave® Sport
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: June 17, 2009
Received: June 17, 2009

Dear Mr. Heaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Director, DSP, O.E.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081998

Device Name: H-Wave® Sport

Indications for Use:

The H-Wave Sport is intended for muscle conditioning by stimulating muscle in order to improve or facilitate muscle performance. The H-Wave Sport is not intended to be used for therapy or treatment of medical diseases or medical conditions.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K081998